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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/716,356 | 11/21/2000 | Shimpei Ushio | USHIO-2 | 8174 |
| 1444 | 7590 | 03/22/2005 | EXAMINER | |
| BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303 | | | LUCAS, ZACHARIAH | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |

DATE MAILED: 03/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/716,356

Applicant(s)

USHIO ET AL.

Examiner

Zachariah Lucas

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-9 and 18-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,2,4-9 and 19 is/are allowed.
- 6) ☒ Claim(s) 18 and 20-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. Currently, claims 1, 2, 4-9, and 18-52 are pending and under consideration in this application. These claims were rejected in the Final Rejection of September 9, 2004.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application on March 9, 2005 after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 2, 2005 has been entered.

2. In the prior action (the Final action of September 2004), claims 1,2, and 4-9 were indicated to be allowable, and claims 18-52 were rejected. In the amendment entered upon filing of the RCE, claims 18 and 19 were amended.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **(Prior Rejection- Withdrawn)** Claims 18-52 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention. In view of the amendment of the claim, the rejection is withdrawn.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. **(Prior Rejection- Maintained)** Claims 18, 20, and 21-52 were rejected in the prior action under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising SEQ ID NO: 6, or for derivatives thereof varying from SEQ ID NO: 6 by one amino acid residue, does not reasonably provide enablement for a composition comprising any homologue of the sequence that maintains the biological activities and other characteristics required by claim 18. The Applicant traverses the rejection of claims 18 and 20-52 under 35 U.S.C. 112 first paragraph for exceeding the scope of enablement on two grounds.

First, the Applicant asserts that the amended subpart (6) of claim 18 narrows the claim sufficiently such that, when combined with subparts (1)-(5), the claim now reads on material supported by the application. This argument is not found persuasive. First, there is no demonstration in the art that any homologue of SEQ ID NO: 6 that is able to bind an antibody that binds SEQ ID NO: 6 would have the other requisite properties. Second, the Applicant does not appear to have provided any examples of interferon gamma inducing polypeptides that bind to such antibodies with the exception of SEQ ID NO: 6 itself. Because there has been no correlation drawn between the ability of a polypeptide to bind any of the indicated antibodies, and

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in view of the limited guidance as to operable homologues and the unpredicatability in the art, both as indicated in the prior actions, this amendment to the claim is not sufficient to overcome the rejection.

The second basis for reconsideration is the fact that, contrary to the Examiner's assertion in the prior (Final) action, the Taniguchi reference (J Immunol Methods 217: 97-102) actually teaches that the murine homologue to IL-18 was able to induce some interferon gamma production in unmodified human cells. See, carry over paragraph on pages 99-100. However, it is also noted that the reference teaches that the cells were about 100 times less sensitive to the murine homologue. It is clear from the reference that the sequence variations between the two proteins had an effect on the protein's activity. What is not clear is which residues had such an effect, and which shared residues may or may not also be open to substitution. Thus, even if the protein of Taniguchi fell within the scope of the claims, and if the teachings of the reference were applied by those in the art, such teachings still would not enable those in the art to practice the claimed invention to the full extent as claimed. The teachings of the application in combination with that known in the art as shown by Taniguchi would still be insufficient to enable those in the art, given the unpredicatability and limited guidance and examples provided by the application, to make or use any homologue of SEQ ID NO: 6 according to the claims. The rejection is therefore maintained for the reasons above and the reasons of record.

7. **(Prior Rejection- Maintained)** Claims 18, 20, and 21-52 were rejected in the prior action under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims were rejected because the Application does not provide adequate support for claims to the genus of all homologues to the interferon-gamma inducing factor (IGIF) of SEQ ID NO: 6. The Applicant provides only one argument in traversal of this rejection. This argument appears to be no more than an assertion that the current application provides examples of the claimed inventions sufficient to support the scope of the claimed genus. Because the Applicant has provided no basis for this assertion, nor any identification of the working examples of the claimed polypeptides that supposedly provide support for the claimed genus, the Applicant's argument is not found persuasive. As the Applicant has provided no more than a mere allegation of patentability, the assertion is not found persuasive. The rejection is therefore maintained.

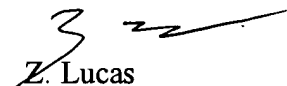
Conclusion


8. Claims 1, 2, and 4-9, and 19 are allowable over the art.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL
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3/21/05